

TDKL-INDIA A ROLE MODEL IN THE FIGHT AGAINST BIOPIRACY

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ABSTRACT

Traditional knowledge (TK) is integral to the identity of most local indigenous communities all over the world. It is an essential constituent of a community's social and physical environment and, therefore, its preservation is of vital importance. Attempts to exploit TK for industrial or commercial benefit can lead to its misappropriation and can prejudice the interests of its rightful owners and custodians. As the relevance and economic import of intellectual property has increased manifold, the threat to the traditional medicinal knowledge, especially those belonging to the indigenous communities of the developing and underdeveloped nations of the world has amplified tremendously. India has a very rich and diverse knowledge in ancient Traditional medicines, however, this valuable asset is under threat from many parts of the world.

It is alarming to watch widespread misappropriation of traditional knowledge through patent filings by third parties without the prior informed consent of TK holders and few, if any, of the derived benefits are shared with the communities in which this knowledge originated, developed and preserved. These issues have placed TK to the forefront of the international agenda, triggering debates about the ways to preserve, protect, further develop and use TK in medicines. India has been a pioneer in this field by documenting and digitizing TK-related information in the form of TKDL. This paper analyses the relevance and effectiveness of the Traditional Knowledge Digital Library (TDKL) as a defensive protection mechanism in safeguarding India's rich and varied heritage in traditional medicines.

KEYWORDS: *Traditional Medicines, Traditional Knowledge Digital Library, Defensive Protection & Traditional Knowledge*

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INTRODUCTION

In the famous words of Justice Peterson, while dwelling upon a famous British copyright infringement case in 1916, “*what is worth copying is prima facie worth protecting*”, appears to clearly lay out the need to protect Traditional knowledge (TK). There are various reasons to protect TK, other than that corporations find it worthwhile to copy it and yet rarely appreciate the corresponding duty to compensate the knowledge holders¹. This dishonest use of traditional medicinal knowledge is often termed as Biopiracy, where indigenous knowledge of nature, originating with indigenous people, is used by others for profit, without permission from and with little or no compensation or recognition to the indigenous people themselves.²

Traditional communities have been responsible for the discovery, development, and preservation of a tremendous range of medicinal plants, health-giving herbal formulations, agricultural and forest products, that are

¹ *University of London Press, Limited v. University Tutorial Press, Limited.*

² Pandey S; “*Biopiracy related to Traditional Knowledge & Patenting issues*” available at: birac.nic.in/webcontent/dib.pdf; accessed on: 15-01-2018.

traded internationally and generate considerable economic value but the profits accrued have not reached those communities.

Reasons Why Traditional Medicinal Knowledge is in Demand

- High cost of pharmaceuticals.
- Low costs of traditional medicines and their effectiveness.
- Preference of traditional medicines in many ailments, even by the urban population.
- Traditional medicines can and have served as inputs in biomedical research, suggesting that they may constitute a source of income not just as drugs in themselves, but as the sources of chemical substances forming the basis of new pharmaceuticals.
- High research costs and low success rate in new drug discovery through synthetic route.
- Easy availability in the public domain.
- The widespread notion that since traditional medicines are obtained from natural resources, they are free from side effects.
- Life style changes round the world as people even in the developed countries are recognizing the true value of nature's products and remedies³

As a result of such risks of misappropriation, there is a need to develop ways and means to protect, preserve and nurture TK for sustainable development in tune with the interests of TK holders especially, in medicines in these countries of the world. TK and biodiversity have always played a significant role in the health care, food security, culture, religion, identity, environment, trade and development of many communities in India.

Historical Perspective

Traditional communities in the world over have been responsible for the discovery, development, and preservation of a tremendous range of medicinal plants, health-giving herbal formulations, agricultural and forest products. The local communities in India too, do not have knowledge nor possess any kind of safeguards to protect their property in a system which has its origin in different cultural values and attitudes. More than 70% of the population in India depend on Traditional healthcare needs and a large number of the people have livelihood connected with traditional medicines.

For a patent to be granted, an applicant must satisfy certain criteria as defined by national patent law, in particular, an applicant must prove that a claimed invention is novel and not previously known. Why then had patents been granted for so many applications relating to Indian medicinal systems? When patent examiners assessed these applications for patentability, the claimed inventions did not feature in the prior art searches carried out. They were, therefore, deemed patentable. At that time, however, much of India's traditional medicinal knowledge only existed in Hindi, Sanskrit, Arabic, Urdu and Tamil. These languages were neither accessible to nor understood by patent examiners working in the major patent offices to which the applications had been submitted.

The fact that so many patents had been wrongfully granted in the U. S. and Europe caused a great deal of national distress. The people of India felt that the knowledge belonging to India was wrongfully being taken away from them. On top of this, these “wrong” patents conferred exclusive rights to exploit the technology in the country in which patent protection was granted. This posed a very real economic threat to Indian producers and users of traditional medicines and their freedom to operate in foreign markets.

Protecting Traditional Medicinal Knowledge–Process and Procedures

India’s TKDL, is a prestigious collaborative project between the Council of Scientific and Industrial Research (CSIR) and the Department of AYUSH⁴. The Department of Indian Systems of Medicine and Homeopathy (ISM&H), created in March 1995, was renamed as the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH) in 2003, is an indigenous effort to ensure patent offices around the world do not grant patents for applications based on the nation’s rich age-old traditional medicinal knowledge. The establishment of TKDL came to the fore amid India’s efforts to revoke the patent granted by the United States Patent and Trademark Office (USPTO) on the wound healing properties of turmeric, and the patent granted by the European Patent Office (EPO) on the antifungal properties of neem.⁵ These endeavors, while successful, proved extremely costly and time-consuming.

In 2001, around the time the TKDL came to be established, the TKDL expert group estimated that, annually, some 2,000 patents relating to Indian medicinal systems were being erroneously granted by patent offices around the world.

About 0.29 million medicinal formulations that have been available in languages in the ancient texts on Indian medicines such as Ayurveda, Siddha, Unani, and Yoga have been scientifically converted and structured, with the help of Information technology tools and an innovative classification system – Traditional Knowledge Resource Classification (TKRC). TKDL technology brings various ancient disciplines and languages such as Ayurveda, Unani, Siddha, Yoga, Sanskrit, Arabic, Urdu, Persian, Tamil together with English, Japanese, Spanish, French, German, modern science & modern medicine.

The incidence of biopiracy is a major impediment to the advancement of Indian herbal medicine. A survey by a TKDL task force based on 4,896 references revealed that 90 medicinal plants were listed in the US Patent and Trademark Office database, and about 80% of references were related to seven medicinal plants (kumari, mustaka, tamraparna, garjara, atasi, jambira, and kharbuja) of Indian origin. The task force also revealed that 360 of 762 patents were based on medicinal plants that could be classified as “traditional”.⁶ This indicates the potential of Indian traditional knowledge and herbal drugs to address a large number of ailments in the future.⁷

Since then, India’s Traditional Medicine Protection Warrior – the Traditional Knowledge Digital Library (TDKL) has been playing a major role in preventing misappropriation of the country’s knowledge and resources in traditional medicines that have developed over the ages.

⁴ http://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html#3 ; accessed on 16/08/18

⁵ <http://www.tkdil.res.in/tkdil/langdefault/common/Abouttkdl.asp?GL=Eng>; accessed on 16/08/18

⁶ Sen S, Chakraborty R. Traditional Knowledge Digital Library: a distinctive approach to protect and promote Indian indigenous medicinal treasure. *Curr Sci.* 2014;106(10):1340–1343

⁷ Sen S, Chakraborty R. Toward the integration and advancement of herbal medicine: a focus on traditional Indian medicine; Botanicals: Targets and Therapy available at : <https://www.dovepress.com/> by 183.87.51.97 on 27-Nov-2018.

THE CURRENT SCENARIO

India is today capable of protecting some 0.29 million medicinal formulations and at zero direct cost through TKDL. On account of access to this database, patent examiners root out those applications that clearly do not satisfy the novelty requirement at the preliminary stage itself. Without the current TKDL database, the process of revoking a patent can be a costly and time-consuming affair. It takes, on an average, about five to seven years and costs between 0.2 and 0.6 million US dollars to oppose a patent granted by a patent office.

Through TKDL there has been conversion and structuring of the ancient Indian texts into 34 million A4-sized pages along the lines of patent application.⁸

It is not a transliteration; rather it is a knowledge-based conversion, where data available from TK sources is converted into several languages by using a Unicode, Metadata Methodology.

TKDL has adopted an innovative classification system such as Resource/knowledge classification, document classification, the subject based classification that will facilitate the interaction of modern scientific knowledge with ancient knowledge like Ayurveda. These classification systems were based on the structure of International Patent Classification (IPC) Such as section, class, subclass, group and subgroup and Traditional Knowledge Resource Classification (TKRC).⁹

An outstanding feature of TKDL is that the modern scientific names (as have been identified by scientists), are given to the traditional plants name, along with disease and preparations such as Kumari (Indian local Name) to Aloe Barbadebisis Mill, in order to establish the relationship with traditional knowledge and modern science. TKDL is created on the traditional codified knowledge of Indian systems of medicine and in 2011, about 85,500 formulations in Ayurveda, 120,200 formulations from Unani, 13,470 formulations from Siddha and 1098 postures to Yoga had been transcribed.

TKDL has thus, setup international specifications and standards for establishing a working TK database based on TKDL specifications. The same had been adopted in 2003 by the Committee in fifth session of the Intergovernmental Committee (IGC) of WIPO on Intellectual Property and Genetic Resources, Traditional Knowledge and Expression of folklore.

Further, pre-grant oppositions are being filed at various International Patent Offices, along with prior-art evidences from TKDL and the results are hugely encouraging. More than 200 patent applications of the pharmaceutical companies of the United States, Great Britain, Spain, Italy, China, etc. have either been set aside/ withdrawn/ amended, based on the Prior art evidences present in the TKDL database without any cost and in a few weeks/months time. Since the beginning of July 2009, TKDL team has identified 1155 Patent applications at International Patent Office's like United States Patent and Trademark Office (USPTO), European Patent Office (EPO), Canadian Intellectual Property Office (CIPO), German Patent and Trade Mark Office (DPMA), United Kingdom Patent & Trademark Office (UKPTO), IP Australia and Controller General of Patents Designs and Trademarks (CGPDTM), with respect to Indian Systems of Medicine and prior-art evidences from Traditional Knowledge Digital library have been filed at pre-grant stage under

⁸ Gupta V. K. "Protecting India's Traditional Knowledge", WIPO Magazine, 2011 Available online: <http://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html>, Accessed 12.01.2016.

⁹ Gupta, V.K., Traditional Knowledge Digital Library, NISCAIR and CSIR sub-regional Experts Meeting in Asia on Intangible Cultural Heritage: Safeguarding and Inventory making Methodologies, Bangkok, Thailand, December, 2005

relevant provisions at these patent Offices in more than 1120 cases till August, 2014. Success rates have been achieved in 206 cases where the patent applications have either been withdrawn/cancelled/declared dead/terminated or have the claims amended by applicants or rejected by the Examiner(s) on the basis of TKDL submissions. TKDL has been able to achieve success against 36 Multinational Corporations worldwide and is expecting to add many more feathers in its cap as a tool in India's fight against biopiracy. However, in many cases the country had to fight for revocation of the granted patents, which may not be a feasible option possible for all the patents taken on the traditional knowledge since it involves huge costs, labour and time.

The Cabinet Committee on Economic Affairs controls access to TKDL, and negotiates the terms and conditions of the Access agreement with world governments, so that the examiners of patent offices can utilize TKDL for search and examination purposes only and do not reveal the contents of TKDL to any third party unless it is necessary for the purpose of citation. TKDL Access Agreement has in-built safeguards on Non-disclosure clauses to protect India's interest against any possible misuse.

A recent study by a TKDL expert team at the EPO shows a sharp decline (44%) in the number of patent applications filed concerning Indian medicinal systems, particularly in relation to medicinal plants, recalls Dr. V. K Gupta is Senior Advisor & Director of TKDL at the Indian Council of Scientific and Industrial Research (CSIR). [TKDL's positive outcomes against biopiracy show the following results: In 2009 (8 cases), 2010(22 cases), 2011(45 cases), 2012 (54 cases), 2013(47 cases), 2014(29 cases), and 2015(14 cases).].

CONCLUSIONS

TKDL is hence, proving to be an effective deterrent against bio-piracy and is being acknowledged as a global leader in the field of traditional medicinal knowledge protection. Today, India is being hailed as a role model in its efforts to curb biopiracy by International bodies like the World Intellectual Property Organization (WIPO). WIPO has recognized 'Utilization of Traditional Knowledge Digital Library as a Model for Protection of Traditional Knowledge', pursuant to this, it has in collaboration with Council for Scientific and Industrial Research (CSIR) and Ministry of Commerce and Industry (DIPP) organized an 'International Study Visit To TKDL' for 19 countries interested in the replication of TKDL model.

TKDL has achieved many goals. They are

- Targeted and put a stop to grant of Patents in the initial pre-grant stage itself during the prior art patent search and examination process. As the patent application for 'wrong' patents is rejected in the pre-grant stage, no appeal is allowed. Long, expensive and tedious patent litigation is curbed on account of the extensive, scientific and systematic TKDL database.
- Ensured that Traditional Medicinal Knowledge Data be written in a technical way that Patent examiners in the world over can understand.
- Availability of TDKL data to raise objections in support of post grant opposition proceedings.
- It has opened up an inexpensive protection pathway and does not require any legal support because prior art evidence is available in the TKDL database which is available to patent examiners.
- TKDL has assisted in the cancellation or withdrawal of a large number of patent applications attempting to claim rights over the use of various medicinal plants.

- TKDL is a unique repository of India's vast traditional medicinal knowledge wisdom.
- TKDL has bridged linguistic gaps between traditional knowledge expressed in languages such as Sanskrit, Arabic, Persian, Urdu and Tamil, and those used by patent examiners of major IP offices.
- TKDL has proved to be an effective deterrent against biopiracy of Traditional medicinal knowledge.

TKDL has laid a foundation and marked an impression around the world, particularly in TK-rich countries by demonstrating the advantages of a concrete, proactive step and the power of strong deterrence/defensive mechanism against biopiracy. The mechanism is not intended to restrict the use of traditional knowledge, but to ensure that wrong patents are not granted due to lack of access to the prior art for Patent examiners.

India's Traditional Knowledge Digital Library—is thus, a unique tool that is playing a critical role for protection and prevention of misappropriations of traditional knowledge in medicines through defensive protection mechanism, though a strong positive protection through legislation would bring greater benefit to the vast traditional knowledge available in the various indigenous communities in India.

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